

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Wong et al.  
Priority application Ser. No.: 08/996,976  
Priority application Filed: 12/23/97  
Attorney Docket No. SP-1093.2  
For: ULTRAPURE VEGETABLE PROTEIN  
MATERIAL  
Priority application Examiner: Ware, D.  
Art Unit: 1651

Hon. Commissioner of Patents and Trademarks  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT SUBMITTED WITH CONTINUATION-IN-PART APPLICATION FILED UNDER 37 CFR § 1.53(b)**

Dear Sir:

Please enter this preliminary amendment and accompanying remarks in the file of the above referenced continuation-in-part application filed herewith.

In the Specification

Immediately after the title please insert the following sentence:

This application is a continuation-in-part of co-pending application Serial No. 08/996,976 filed on 12/23/97.

On page 4, please insert the following paragraph after the first full paragraph ending on line 18 and before the paragraph beginning on line 19:

The starting material for the process of the present invention is a vegetable material which contains protein and ribonucleic acids. The vegetable material may be relatively unrefined, for example whole soybeans and whole peas. More preferably the vegetable material is more refined and is processed to remove fats, oils, and hulls, and is comminuted or flaked. Preferred moderately refined vegetable protein materials are vegetable flours, vegetable grits, and vegetable flakes. Especially preferred moderately refined vegetable protein materials are defatted soy flours, defatted soy grits and soy meals, and defatted soy flakes.

On page 4 please substitute the following paragraph for the second full paragraph (lines 19-27):

Most preferably the starting material for the process of the present invention is a refined vegetable protein material such as a vegetable protein concentrate or a vegetable protein isolate. As used herein, and according to conventional definition, a vegetable protein concentrate is a vegetable protein material containing from 65% up to 90% protein by weight on a dry basis, and a vegetable protein isolate is a vegetable protein material containing at least 90% protein by weight on a dry basis. Vegetable protein

concentrates and isolates are readily commercially available. For example, soy protein isolates which may be used in the process of the present invention are available from Protein Technologies International, Inc., St. Louis, Missouri, and are sold under the trade names SUPRO<sup>®</sup> 500E and SUPRO<sup>®</sup> 620.

On pages 6 and 7, please substitute the following two paragraphs in place of the final paragraph on page 6 (lines 23-30) and the continuation of that paragraph on page 7 lines 1-2:

The enzyme preparation is added to the slurry in sufficient amount to provide an acid phosphatase concentration effective to degrade and substantially reduce the concentration of ribonucleic acids present in the protein material. The enzyme preparation has an inherent specific enzyme activity measured as phytase units per gram (if the enzyme preparation is a solid) or phytase units per milliliter (if the enzyme preparation is a liquid), where a phytase unit is defined as, and may be measured as, the quantity of enzyme which liberates one nanomole of inorganic phosphates from sodium phytate in one minute under standard conditions (40°C, pH 5.5, and 15 minutes incubation). Commercially available phytase enzyme preparations typically disclose the inherent phytase activity of the enzyme preparation (e.g. 40 PU/g of preparation), or, if the enzyme preparation's phytase activity is unknown, it may be measured under standard conditions as set forth above. To effectively degrade and substantially reduce the concentration of ribonucleic acids in the vegetable protein material, the enzyme preparation is preferably used in an amount sufficient to provide a enzyme activity of greater than 500 kilophytase units per kilogram of protein material ("KPU/kg protein material"), and more preferably at least 600 KPU/kg protein material, or at least 700 KPU/kg protein material, or at least 800 KPU/kg protein material, or at least 900 KPU/kg protein material, or at least 1000 KPU/kg protein material, or at least 1100 KPU/kg protein material, or at least 1200 KPU/kg protein material, or at least 1300 KPU/kg protein material, or at least 1400 KPU/kg protein material, where a kilophytase unit is defined as 1000 phytase units.

Preferably at least a majority of the ribonucleic acids present in the initial vegetable protein material are degraded by the acid phosphatase containing enzyme preparation, where the term a majority is defined to be 50% or greater. More preferably, the acid phosphatase containing enzyme preparation degrades at least 60% of the ribonucleic acids in the vegetable protein material, even more preferably at least 70% of the ribonucleic acids in the protein material, and even more preferably at least 80% of the ribonucleic acids in the protein material, and most preferably the acid phosphatase containing enzyme preparation degrades substantially all of the ribonucleic acids in the protein material.

On pages 7 and 8 please substitute the following paragraph for the last paragraph starting on page 7 (lines 29-30) and continued on page 8 (lines 1-9):

The activity of the enzyme preparation should be effective to degrade and substantially reduce the concentration of ribonucleic acids, the phytic acid concentration, and the concentration of phytates. The enzyme preparation preferably is used in an amount sufficient to provide an activity from about 400 to about 1400 kilophytase units per kilogram of protein (curd) solids (KPU/kg protein solids), more preferably an activity

109. The composition of claim 108 containing 0.1% or less phytic acid, by weight.

110. The composition of claim 103 containing less than 3000 ppm phosphorus.

Please cancel claims 1-36 and 92-102

#### In the Abstract

Please add the following abstract:

A soy protein material containing reduced amounts of ribonucleic acids is provided. The soy protein material contains at most 4000 mg/kg of ribonucleic acids and is substantially devoid of ribonuclease enzymes.

#### Remarks

The present application is a continuation-in-part application of parent case 08/996,976 filed as a result of the restriction requirement of January 30, 2001. Claims 103-105 from the parent application remain pending in the present application, and claims 106-110 have been added to the present application. Original claims 1-36 and 92-102 pending in the parent case are canceled in this continuation-in-part application. Original claims 37-91 were canceled in the parent case.

By the present preliminary amendment new matter has been added to the specification and claims 103-105 have been rewritten. A marked-up version of the replacement and added paragraphs in the specification and the rewritten claims is attached as separate pages to this amendment and is titled "Version With Markings to Show Changes Made." A copy of the original specification as filed in the parent application of the present case is enclosed. Claims 1-36 and 92-105 of the present application retain pendency from the parent application (claims 1-36 and 92-102 being canceled herein). An information disclosure statement and copies of cited references are also enclosed. Applicants hereby request examination and allowance of claims 103-110.

of from about 600 to about 1200 KPU/kg protein solids, and most preferably an activity of about 1000 KPU/kg protein solids. The activity of the enzyme preparation includes acid phosphatase activity and the activity of any other phytase enzyme included in the enzyme preparation.

On page 10 please insert the following paragraph after the paragraph ending on line 7 and before the paragraph starting on line 8:

The vegetable protein material of the present invention is devoid or substantially devoid of active, inactivated, or hydrolyzed ribonuclease enzymes and contains at most 4000 milligrams per kilogram ("mg/kg") ribonucleic acids, more preferably 2000 mg/kg or less of ribonucleic acids, and most preferably 1500 mg/kg or less of ribonucleic acids. Preferably the vegetable protein material of the present invention contains 0.45% or less phytic acid, by weight, more preferably 0.2% or less phytic acid by weight, and most preferably 0.1% or less phytic acid, by weight. In a particularly preferred embodiment the vegetable protein material of the present invention contains less than 3000 parts per million (ppm) phosphorus. Most preferably the vegetable protein material is a soy protein material, and particularly preferred soy protein materials are soy protein isolates and soy protein concentrates.

#### In the Claims

Please amend claims 103-105 as follows:

103. (Amended) A composition comprising, a soy protein material containing at most 4000 mg/kg ribonucleic acids and being substantially devoid of ribonuclease enzymes.

104. (Amended) The composition of claim 103 wherein said soy protein material is a soy protein isolate or a soy protein concentrate.

105. (Amended) The composition of claim 103 wherein said soy protein material contains less than 2000 mg/kg ribonucleic acids.

Please add the following claims 106-110

106. The composition of claim 103 wherein said soy protein material contains less than 1500 mg/kg of ribonucleic acids.

107 The composition of claim 103 containing 0.45% or less phytic acid, by weight.

108. The composition of claim 107 containing 0.2% or less phytic acid, by weight.

Respectfully submitted,

WONG ET AL

Date 6/29/01

By: 

Richard Taylor

Reg. No. 37,248

Patent Counsel

Protein Technologies International, Inc.

(314) 982-3004

FOIA b 7 - DATED 06/29/01

## VERSION WITH MARKINGS TO SHOW CHANGES MADE

### In the Specification

Immediately after the title the following sentence has been inserted:

--This application is a continuation-in-part of co-pending application Serial No. 08/996,976 filed on 12/23/97.--

On page 4 the following paragraph has been inserted between the paragraph ending on line 18 and the paragraph starting on line 19:

--The starting material for the process of the present invention is a vegetable protein material which contains protein and ribonucleic acids. The vegetable material may be relatively unrefined, for example whole soybeans and whole peas. More preferably the vegetable material is more refined and is processed to remove fats, oils, and hulls, and is comminuted or flaked. Preferred moderately refined vegetable protein materials are vegetable flour, vegetable grits, and vegetable flakes. Especially preferred moderately refined vegetable protein materials are defatted soy flours, defatted soy grits and soy meals, and defatted soy flakes.--

On page 4 the paragraph starting on line 19 (lines 19-27) has been amended as follows:

Most preferably the [The] starting material for the process of the present invention is a refined vegetable protein material such as a vegetable protein concentrate or a vegetable protein isolate. As used herein, and according to conventional definition, a vegetable protein concentrate is a vegetable protein material containing from 65% [-] up to 90% protein by weight on a dry basis, and a vegetable protein isolate is a vegetable protein material containing at least 90% protein by weight on a dry basis. Vegetable protein concentrates and isolates are readily commercially available. For example, soy protein isolates which may be used in the process of the present invention are available from Protein Technologies International, Inc., St. Louis, Missouri, and are sold under the trade names SUPRO® 500E and SUPRO® 620.

On pages 6-7 the paragraph starting on line 23 of page 6 and continuing to line 2 of page 7 has been split into two paragraphs and amended as follows:

The enzyme preparation is added to the slurry in sufficient amount to provide an acid phosphatase concentration effective to degrade and substantially reduce the concentration of ribonucleic acids present in the protein material. The enzyme preparation has an inherent specific enzyme activity measured as phytase units per gram (if the enzyme preparation is a solid) or phytase units per milliliter (if the enzyme preparation is a liquid), where a phytase unit is defined as, and may be measured as, the quantity of enzyme which liberates one nanomole of inorganic phosphates from sodium phytate in one minute under standard conditions (40°C, pH 5.5, and 15 minutes incubation). Commerically available phytase enzyme preparations typically disclose the inherent phytase activity of the enzyme preparation (e.g. 40 PU/g of preparation), or, if the enzyme preparation's phytase activity is unknown, it may be measured under

standard conditions as set forth above. To effectively degrade and substantially reduce the concentration of ribonucleic acids in the vegetable protein material, the enzyme preparation is preferably used in an amount sufficient to provide an enzyme activity of greater than 500 kilophytase units per kilogram of protein material ("KPU/kg protein material"), and more preferably at least 600 KPU/kg protein material, or at least 700 KPU/kg protein material, or at least 800 KPU/kg protein material, or at least 900 KPU/kg protein material, or at least 1000 KPU/kg protein material, or at least 1100 KPU/kg protein material, or at least 1200 KPU/kg protein material, or at least 1300 KPU/kg protein material, or at least 1400 KPU/kg protein material, where a kilophytase unit is defined as 1000 phytase units.

Preferably at least a majority of the ribonucleic acids present in the initial vegetable protein material are degraded by the acid phosphatase containing enzyme preparation, where the term a majority is defined to be 50% or greater. More preferably, the acid phosphatase containing enzyme preparation degrades at least 60% of the ribonucleic acids in the vegetable protein material, even more preferably at least 70% of the ribonucleic acids in the protein material, and even more preferably at least 80% of the ribonucleic acids in the protein material, and most preferably the acid phosphatase containing enzyme preparation degrades substantially all of the ribonucleic acids in the protein material.

On pages 7-8 the paragraph starting on line 29 of page 7 and ending on line 9 of page 8 has been amended as follows:

The activity of the enzyme preparation should be effective to degrade and substantially reduce the concentration of ribonucleic acids, the phytic acid concentration, and the concentration of phytates. The enzyme preparation preferably [has] is used in an amount sufficient to provide an activity from about 400 to about 1400 kilophytase units per kilogram of protein (curd) solids (KPU/kg protein [solid] solids), more preferably [has] an activity of from about 600 to about 1200 KPU/kg protein [solid] solids, and most preferably [has] an activity of about 1000 KPU/kg protein [solid] solids. [A kilo phytase unit equals 1000 phytase units, where a phytase unit equals the quantity of enzyme which liberates one nanomole of inorganic phosphates from sodium phytate in one minute under standard conditions (40°C, pH 5.5, and 15 minutes incubation).] The activity of the enzyme preparation includes acid phosphatase activity and the activity of any other phytase enzyme included in the enzyme preparation.

On page 10 the following paragraph has been inserted between the paragraph ending on line 7 and the paragraph beginning on line 8.

--The vegetable protein material of the present invention is devoid or substantially devoid of active, inactivated, or hydrolyzed ribonuclease enzymes and contains at most 4000 milligrams per kilogram ("mg/kg") ribonucleic acids, more preferably 2000 mg/kg or less of ribonucleic acids, and most preferably 1500 mg/kg or less of ribonucleic acids. Preferably the vegetable protein material of the present invention contains 0.45% or less phytic acid, by weight, more preferably 0.2% or less phytic acid, by weight, and most preferably 0.1% or less phytic acid, by weight. In a particularly preferred embodiment the vegetable protein material of the present invention contains less than 3000 parts per million (ppm) phosphorus. Most preferably the vegetable protein material is a soy

protein material, and particularly preferred soy protein materials are soy protein isolates and soy protein concentrates.--

#### In the Claims

Claims 103-105 have been amended as follows:

103. (Amended) A composition [vegetable protein material] comprising, [an acid phosphatase treated] a soy protein material containing [less than] at most 4000 mg/kg ribonucleic acids and being substantially devoid of ribonuclease enzymes.

104. (Amended) The composition [vegetable protein material] of claim 103 wherein said soy protein material is a soy protein isolate or a soy protein concentrate.

105. (Amended) The composition [vegetable protein material] of claim 103 wherein said [acid phosphatase treated] soy protein material contains less than 2000 mg/kg ribonucleic acids.

#### In the Abstract

The abstract is been amended to read as follows:

--A soy protein material containing reduced amounts of ribonucleic acids is provided. The soy protein material contains at most 4000 mg/kg of ribonucleic acids and is substantially devoid of ribonuclease enzymes.--